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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 3986 09/673,710 03/07/2001 Sylvia Burssens 2364/100 **EXAMINER** 02/24/2004 ANN R. POKALSKY, ESQ. COLLINS, CYNTHIA E DILWORTH & BARRESE PAPER NUMBER ART UNIT 333 EARLE OVINGTON BLVD.

1638

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary		09/673,710	BURSSENS ET AL.	
		Examiner	Art Unit	
		Cynthia Collins	1638	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1) Responsive to communication(s) filed on <u>05 December 2003</u> .				
2a)⊠ This actio	n is <b>FINAL</b> . 2b) This	action is non-final.		
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
<ul> <li>4)  Claim(s) 1,5,6,10,11,13-16,18-20,22-26,28,29 and 31 is/are pending in the application.</li> <li>4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1,5,6,10,11,18-20,22-26,28,29 and 31 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>				
Application Paper	s			
9)☐ The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 l	J.S.C. § 119			
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)		_		
1) Notice of Referen 2) Notice of Draftspe	ces Cited (PTO-892) erson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da		
	osure Statement(s) (PTO-1449 or PTO/SB/08)		Patent Application (PTO-152)	

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### **DETAILED ACTION**

The Amendment filed December 5, 2003 has been entered.

The specification has been amended at page 1.

Claims 2-4, 7-9, 12, 17, 21, 27 and 30 are cancelled.

Claims 1, 5-6, 10-11, 18, 20, 22-26, 29 and 31 are currently amended.

Claims 1, 5-6, 10-11, 13-16, 18-20, 22-26, 28-29 and 31 are pending.

Claims 13-16 are withdrawn.

Claims 1, 5-6, 10-11, 18-20, 22-26, 28-29 and 31 examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### Claim Rejections - 35 USC § 112

Claims 1, 5-6, 10-11, 18-20, 22-26, 28-29 and 31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed June 3, 2003.

Applicant's arguments filed December 5, 2003 have been fully considered but they are not persuasive.

Applicant points to the amendment of claims 1, 5, 6, 10, 11 and 25, and argues that the claims as amended are fully supported by the written description in the specification, which

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PSTAIRE amino acid motif in the CDC2At gene. Applicant additionally points to the submitted references of Mironov et al. (The Plant Cell, Vol. 11, pages 509-521, April 1999, Exhibit A) and Stals et al. (Trends in Plant Science, Vol. 6, No. 8, pages 359-364, August 2001, Exhibit B) for descriptive support, which disclose that eukaryotic cyclin-dependent kinases from diverse species of organisms are known to be a highly conserved group of proteins. (reply pages 9-12)

The claimed invention is not described because Applicant has disclosed only one nucleic acid molecule whose introduction into a plant confers stress tolerance, a nucleic acid molecule that encodes an *Arabidopsis* CDC2a (CDKA;1) mutein wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine. The specification does not describe or characterize other non-phosphorylatable amino acid residues that may occupy the positions corresponding to residues 14 and 15 respectively in *Arabidopsis thaliana* CDKA;1 as claimed in claims 1 and 5. The specification also does not describe or characterize CDKA;1 muteins wherein only the tyrosine at position 15 is substituted with a non-phosphorylatable amino acid residue as claimed in claim 1. Additionally, the specification does not describe or characterize nucleic acid molecules encoding muteins of PSTAIRE comprising cyclin-dependent kinases CDC2a (CDKA;1).

With respect to the submitted references of Mironov et al. (Exhibit A) and Stals et al. (Exhibit B), the Examiner does not dispute their general teaching that eukaryotic cyclin-dependent kinases are known to be a highly conserved group of proteins. The Examiner maintains, however, that the general conservation of structure among eukaryotic cyclin-

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dependent kinases does not serve to describe the specific features of the claimed invention. The submitted references do not describe which non-phosphorylatable amino acid residues other than alanine and phenylalanine may occupy the positions corresponding to residues 14 and 15 respectively in *Arabidopsis thaliana* CDKA;1. The submitted references do not describe a CDKA;1 mutein wherein only the tyrosine at position 15 is substituted with a non-phosphorylatable amino acid residue. The submitted references do not describe which PSTAIRE comprising cyclin-dependent kinases could, when appropriately mutated, be used to confer drought or salt stress tolerance to a plant transformed therewith.

Claims 1, 5-6, 10-11, 18-20, 22-26, 28-29 and 31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for obtaining plants tolerant to drought or salt stress conditions, said method comprising introducing into a plant cell, plant tissue or plant a nucleic acid sequence encoding an *Arabidopsis* CDC2a (CDKA;1) protein wherein the tyrosine at position 15 is substituted to phenylalanine and the threonine at position 14 is substituted to alanine, does not reasonably provide enablement for method comprising introducing into a plant cell, plant tissue or plant other nucleic acid sequences encoding other amino acid sequences, for the reasons of record set forth in the office action mailed June 3, 2003.

Applicant's arguments filed December 5, 2003 have been fully considered but they are not persuasive.

Applicant argues that the claimed invention is fully enabled because the specification clearly teaches that the amino acid corresponding to the tyrosine at position 15 in CDKA;1 is substituted with a non-phosphorylatable amino acid residue, that in a more preferred

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embodiment both amino acid residues corresponding to the tyrosine at position 15 and the threonine at position 14 in CDKA;1 are substituted with non-phosphorylatable amino acid residues, and that phenylalanine and alanine are further preferred as the non-phosphorylatable amino acid residues. (reply pages 12-14)

The claimed invention is not fully enabled because the specification does not provide sufficient guidance with respect to which non-phosphorylatable amino acid residues other than alanine and phenylalanine may occupy the positions corresponding to residues 14 and 15 respectively in Arabidopsis thaliana CDKA;1. Additionally, the specification does not provide sufficient guidance with respect to how to use a CDKA;1, or any other PSTAIRE comprising cyclin-dependent kinase mutein, wherein only the tyrosine corresponding to position 15 in Arabidopsis thaliana CDKA; 1 is substituted with a non-phosphorylatable amino acid residue. Further, the specification does not provide sufficient guidance with respect to which PSTAIRE comprising cyclin-dependent kinases other than CDKA;1 could, when appropriately mutated, be used to confer drought or salt stress tolerance to a plant transformed therewith. Such guidance is necessary because the effect of changing the amino acid composition of a PSTAIRE comprising cyclin-dependent kinase on its ability to confer drought or salt stress tolerance when expressed in a plant is unpredictable. Absent such guidance it would require undue experimentation for one skilled in the art to determine which PSTAIRE comprising cyclin-dependent kinases to modify, and which non-phosphorylatable amino acid residues to use for their modification, in order to obtain nucleic acid molecules that would confer drought or salt stress tolerance to a plant transformed therewith.

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## Claim Rejections - 35 USC § 102

Claims 25-26, 28-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hemerly et al. (The EMBO J., 1995, Vol. 14, No. 16, pages 3925-3936, Applicant's IDS).

The claims are drawn to a vector comprising a nucleic acid molecule encoding a cyclin-dependent kinase mutein comprising an alanine and a phenylalanine at positions corresponding to residues 14 and 15 respectively in *Arabidopsis thaliana* CDKA;1, wherein said nucleic acid molecule is operably linked to a chimeric promoter. The claims are also drawn to transgenic plant cells, plants and plant parts comprising said nucleic acid molecule.

Hemerly et al. teach a vector comprising a nucleic acid molecule encoding a cyclin-dependent kinase mutein comprising an alanine and a phenylalanine at positions corresponding to residues 14 and 15 respectively in *Arabidopsis thaliana* CDKA;1, wherein said nucleic acid molecule is operably linked to a constitutive CaMV 35S promoter, and transgenic *Arabidopsis* and tobacco plants comprising said nucleic acid molecule (page 3926 Figure 1; paragraph spanning pages 3926-3927; page 3927 Figure 3). The constitutive CaMV 35S promoter used by Hemerly et al. is chimeric because it is spliced to a heterologous nucleic acid molecule.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Remarks

No claim is allowed.

Claims 1, 5-6, 10-11, 18-20 and 22-24 are deemed free of the prior art due to the failure of the prior art to teach or suggest a method for obtaining plants tolerant to drought or salt stress conditions by introducing into a plant cell, plant tissue or plant a nucleic acid molecule encoding a PSTAIRE comprising cyclin-dependent kinase mutein having a non-phosphorylatable amino acid residue in a position corresponding to the tyrosine at position 15 of Arabidopsis CDKA;1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CC February 17, 2004

DAVID T. FOX
RIMARY EXAMINER

GROUP 180-